Remarks

Applicants provide detailed remarks and arguments concerning the amendements submitted in view of the previous Examiner's communication of 3/9/04. In the previous communication, the examiner rejected the claims on the following basis: 1) Rejection of Claim 28 as being duplicative; 2) Rejection of Claims 1-6, 11-12, 26, 30-32, and 35 under 35 USC § 103; 3) Rejection of Claim 26 under 35 USC § 103

Claim 28

Examiner has indicated that the Applicant has cancelled claim 28, but has also submitted amendments therefor. After the Examiner's review of amended claim 28, it appears to differ from claim 26 only in the functional language of the preamble. The examiner has deduced that it was, in fact, Applicant's intent to cancel claim 28, and thus, it has not been examined, and remains cancelled.

Applicants have formally cancelled Claim 28, thereby rendering the present rejection moot.

Rejection of Claims 1-6, 11-12, 26, 30-32, and 35 under 35 USC § 103

Claims 1-6, 11, 12, 26, and 30-31 were rejected by the Examiner under 35 U.S.C. 103(a) as being unpatentable over Helmus et al. (US 5,447,724) in view of Fearnot et al. (US 5,609,629).1

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[1] Helmus was cited for teaching substantially all the claimed subject matter including an implantable medical device (figure 1, col. 3, line 31), having a tissue-contacting surface formed of polyurethane or silicone (col. 2, lines 41-42) which has a drug such as heparin (col. 6, line 51) or a steroid (col. 6, line 55) intimately mixed into it (col. 4, lines 20-24 and col. 9, lines 45-46). The Examiner specifically points out that col. 71 lines 57 -62 specify the OUTER layer, not the reservoir layer. In col. 7, lines 57 -62, Helmus teaches that the agent in the outer layer is put there to produce a "gradual release effect" alluding to the slower release of the agent at first from the outer layer and gradual increase in the release rate as the more concentrated stores of the same agent start to seep through the outer layer from the inner reservoir. Since this teaches that the agent in the outer layer can be the same as in the inner layer, and that the

Fearnot (US 5,609,629) teaches the application teaches that the medical device should have at least **two** coatings. First there should be a "bioactive layer." Then applied over the "bioactive layer" there should be at least one porous top-coat layer

> "Applicants have discovered that the degradation of an agent, a drug or a bioactive material applied to such a device can be avoided by covering the agent, drug or bioactive material with a porous layer of a biocompatible polymer . . ."[Fearnot et al., US 5,609,629 - Column 3, lines 6-12]

Fearnot teaches that drug release polymers coated to medical devices should have a top porous layer is preferably made of polyimide, parylene, or a parylene derivative (Col. 3, lines 50-57) which are applied by vapor deposition (Col. 3, lines 50-54) or plasma deposition (Col. 4, lines 13-24). Fearnot limits this selection when he says "A vast range of drugs, medicants and materials can be employed as the bioactive material in the layer 18 ("bioactive layer"), so long as the selected material can survive exposure to the vacuum drawn during vapor deposition or plasma deposition" (Col. 7, lines 32-36).

Helmus also requires having **two** coats. Helmus requires a bottom reservoir layer and a top coat layer to control delivery. Minimally the "reservoir" layer requires the physical formation of drug reservoir pockets – these pockets are formed from porogens initially placed in the coating (referred by Helmus as "elutable components"

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reservoir agent can be a steroid (col. 6, line 55), is interpreted by the Examiner as referring to physiologically active agents in both the reservoir and outer layer. The Examiner indicates that Helmus teaches all the claimed subject matter except for the steroid being a glucocorticosteroid such dexamethasone. Fearnot is relied on by the Examiner for teaching the of as use dexamethasone in a drug embedded outer layer of a catheter. The Examiner, thereby concludes, it would have been obvious to one of ordinary skill in the art to use dexamethasone as taught by Fearnot as one of the steroids broadly mentioned by Helmus (col. 6, line 54-55) since dexamethasone is a well-known anti-inflammatory steroid, and as demonstrated by Helmus it is known to use it as the bioactive component of a bioactive surface on a catheter.

In the Examiner "Response to Arguments, the Examiner points out that Applicants specification on page 13, line 26 indicates that the agent and polymer, are "intimately mixed by [1] blending or [2] using a solvent in which they are both soluble . . .", and that Applicants appear to be arguing that the term "intimately mixed" means only the second possibility [2], that is, use of a solvent.

– see Column 6, lines 25-29 and Col. 7, lines 15-20). As such, Helmus does not appear to teach the tissue-contacting polymer surface of the catheter is dissolvably mixed with the drug because there are defined particulates in the polymer layer. The outer polymeric surface-layer overlying a inner polymer layer that incorporates the agent (23) (see figures 1b and 1c, or 2b and 2c)and has an elutable component (22) which is eroded to form pores to the inner polymer area containing agent (23). The "elutable component" is required to be particulate in nature in order to form the structural pores in the polymer layer. No where is there formed a therapeutic polymer reservoir without particulates.

Applicants invention as now claimed is distinguishable over Helmus in view of Fearnot in several respects. First, both Helmus and Fearnot contain a drug resevoir layer. Applicants contain the drug in the applied overcoating – but not through forming drug reservoir pockets. Both Helmus and Fearnot use an overcoating to control the release of the drug from the undercoat. Neither Helmus or nor Fearnot teach a controlled release mechanism from the overcoat by having the polymer and drug co-solvated in the same solvent with the requirement that there are no particulates. This clearly distinguish over Helmus where the top-layer contains elutable micron-sized particulates that forms channels from removal of the elutable components.

In conclusion, neither Fearnot nor Helmus teach an overcoating of a polymer with an active agent that does not contain particulates. Both Fearnont and Helmus require at least two layers applied to the medical device. Applicants do not have drug reservoirs because the active agent is solublized in the polymer. In view of these differences over Helumus in view of Fearnot, Applicants respectfully request the present rejections be removed.

Rejection of Claim 26 under 35 USC § 103

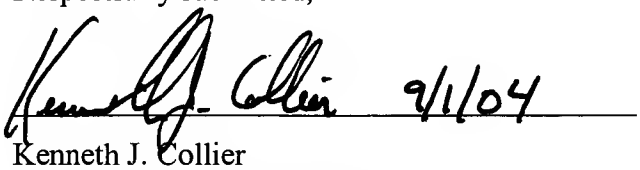
With regard to the method claims, claim 26, which claims a method of use, the examiner points out that the claim only contains one broad method step of "implanting," the rest is merely structure. The Examiner further points out that claims 30-32, and 35 merely claim the basic assembly steps necessary to put anything together (e.g. "coupling").

Applicants have amended their claims to provide step of the process the step of overcoating the medical device with a single layer containing the active agent, wherein the applied over-coating does not contain micro-particulates. In view of having a novel and non-obvious overcoating process step, the applicants respectfully request the present reject be removed.

Conclusion

In view of the submitted cancelled claims, amended claims, and arguments submitted with the present response, Applicants' believe the claimed subject matter is novel and unobvious over the prior art and anxiously await the examiner's review and approval to issue the remaining claims. Should the Examiner have any question regarding the submitted amendments and arguments or wish to discuss the application. Applicants are available for discussion through their attorney at the number provided below.

Respectfully submitted,



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AMENDED CLAIMS

1. (currently amended) A medical electrical lead comprising:

1) an elongated insulative lead body not formed with an active agent, and

2) a polymer overcoating of said lead body providing a tissue-contacting surface,[a proximal end, and a distal end,] and an active agent;

wherein said overcoating is chosen such that said polymer and said active agent are free of micron sized particulates.

[an elongated conductor having a proximal end and a distal end, mounted within the insulative lead body; and

an electrode coupled to the distal end of the electrical conductor form making electrical contact with bodily tissue; and

wherein the tissue-contacting surface of the insulative lead body comprises an overcoating of a non-porous polymer intimately mixed with a steroidal anti-inflammatory agent.]

2. (Original) The medical electrical lead of claim 1 wherein the polymer is selected from the group of polyurethanes, silicones, polyamides, polyimides, polycarbonates, polyethers, polyesters, polyvinyl aromatics, polytetrafluoroethylenes, polyolefins, acrylic polymers or copolymers, vinyl halide polymers or copolymers, polyvinyl ethers, polyvinyl esters, polyvinyl ketones, polyvinylidine halides, polyacrylonitriles, copolymers of vinyl monomers with each other and olefins, and combinations thereof.

3. (Original) The medical electrical lead of claim 2 wherein the polymer is selected from the group of polyurethanes, silicones, or combinations thereof.

4. (Original) The medical electrical lead of claim 1 wherein the anti-inflammatory agent is a glucocorticosteroid.

5. (Original) The medical electrical lead of claim 4 wherein the glucocorticosteroid is selected from the group of cortisol, cortisone, fludrocortisone, Prednisone, Prednisolone, 6α-methylprednisolone, triamcinolone, betamethasone, dexamethasone, beclomethasone, aclomethasone, amcinonide, clebethasol, clocortolone, derivatives thereof, and salts thereof.

6. (Original) The medical electrical lead of claim 5 wherein the glucocorticosteroid is dexamethasone, a derivative thereof, or a salt thereof.

7. (Cancelled)
8. (Cancelled)
9. (Cancelled)
10. (Cancelled)

11. The medical electrical lead of claim 1 wherein the tissue-contacting surface further includes heparin.

12. (Cancelled)
13. (Cancelled)
14. (Cancelled)
15. (Cancelled)
16. (Cancelled)
17. (Cancelled)
18. (Cancelled)
19. (Cancelled)
20. (Cancelled)
21. (Cancelled)
22. (Cancelled)
23. (Cancelled)
24. (Cancelled)
25. (Cancelled)

26. (Cancelled)

27. (Cancelled)

28. (Cancelled)

29. (Cancelled)

30. (Amended) A method of making a medical electrical lead comprising:

1) providing an elongated insulative lead body not formed with an active agent, and

2) overcoating of said lead body with a tissue-contacting surface containing an active agent;

wherein said overcoating is chosen such that said polymer and said active agent are free of micron sized particulates.

[providing an elongated insulative lead body having a tissue-contacting surface, a proximal end, and a distal end; wherein the tissue-contacting surface comprises an overcoating formed from a non-porous polymer cosolvated with a steroidal anti-inflammatory agent. [of a non-porous polymer intimately mixed with a steroidal anti-inflammatory agent;]

providing an elongated conductor having a proximal end and a distal end;

mounting the elongated conductor within the insulative lead body; and

coupling an electrode to the distal end of the electrical conductor for making electrical contact with bodily tissue.]

31. (Amended) The method of claim 30 wherein the step of providing an elongated insulative lead body comprises blending or solvating the [steroidal anti-inflammatory] active agent with [the non-porous] the polymer and forming said tissue-contacting surface free of micron sized particulates.

32. (Cancelled)

33. (Cancelled)

34. (Cancelled)

35. (Cancelled)